

TO D. Zuh, PhD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 142/003/PCT; 03-766)

PATENT

In re Application of:	Light et al.)	
)	
Serial No.:	09/582,492)	Before the Examiner: J. Switzer
)	
Filed:	March 6, 2002)	Group Art Unit: 1634
)	
For:	Detection of Human Papilloma)	
	Virus in Papanicolaou (Pap) Smears)	

Mail Stop AF
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

I, Gerard J. Nuovo, hereby declare:

1. I am a Professor of Pathology at the Ohio State University Medical Center. I am also a named co-inventor on the above-described patent application. I have an M.D. from the University of Vermont Medical College and have been engaged in research on gynecologic pathology, focusing on cervical diseases, and infectious disease detection, focusing on HPV and *in situ*-based methodologies, for eighteen years. My *curriculum vitae* is attached hereto as Appendix A.
2. I authored an article entitled "Detection of Human Papillomavirus in Papanicolaou Smears: Correlation With Pathologic Findings and Clinical Outcome," which was published in *Diagnostic Molecular Pathology* in June of 1998 (Nuovo, 1998; *Diagn. Mol. Pathol.* 7:158-63).
3. My 1998 reference discloses the use of Oncor's high-risk HPV consensus probe to detect different oncogenic HPV types in cervical biopsies by *in situ* hybridization under low stringency conditions (p. 159, 161). In particular, my 1998 reference discloses that the Oncor high-risk consensus probe can be used under low stringency conditions to detect the oncogenic HPV types 16, 18, 30, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, and 70, but not the HPV types 6, 11, 42, 43, and 44 (p. 161). My 1998 reference also discloses that Oncor's high-risk HPV consensus probe contains multiple high-risk HPV types (p. 160).

4. My 1998 reference does not disclose the specific composition of the Oncor high-risk HPV consensus probe (*i.e.*, the particular HPV types comprising the consensus probe or proportions of these particular HPV types).

5. Accompanying this Declaration is a copy of my notes from before June of 1998 (Exhibit A) documenting that a high-risk HPV consensus probe comprising 200 ng/ml or 500 ng/ml of HPV type 16 DNA would detectably hybridize to HPV types 6/11 under conditions of low stringency.

6. Using the teachings of my 1998 reference and knowledge in the art at the time my 1998 reference was published, a person of ordinary skill in the art would not be able to determine the particular HPV types or proportions of the particular HPV types comprising the Oncor high-risk HPV consensus probe, and as a result, would not be able to prepare a high-risk HPV consensus probe that does not detectably hybridize to the genomic sequence of a low-risk HPV type.

7. I co-authored an article entitled "A Comparison of Subgenomic and Genomic DNA Probes for Detection and Typing of Human Papillomavirus by in situ Hybridization," which was published in the Journal of Histotechnology in June of 1995 (Nuovo *et al.*, 1995, *J. Histotech.* 18:105-110).

8. My 1995 reference discloses the use of eight different high-risk HPV consensus probes, including high-risk HPV consensus probes obtained from both Digene Diagnostics and ONCOR that contain probes generated from specific subgenomic areas of (i) HPV types 16 and 18 or (ii) HPV types 31, 33, and 35 (page 106).

9. My 1995 reference does not disclose the specific proportions of the probes in the Digene Diagnostics or ONCOR high-risk HPV consensus probes.

10. Using the teachings of my 1995 reference and knowledge in the art at the time my 1995 reference was published, a person of ordinary skill in the art would not be able to determine the proportions of the probes in the Digene Diagnostics or ONCOR high-risk HPV consensus probes, and as a result, would not be able to prepare a high-risk consensus probe that does not detectably hybridize to the genomic sequence of a low-risk HPV type.

11. At the time my 1995 reference was published, a person of ordinary skill in the art would not have appreciated (and, in fact, the named inventors of the above-described application did not yet appreciate) that a high-risk HPV consensus probe that did not detectably hybridize to the

genomic sequence of a low-risk HPV type under low stringency conditions could be prepared by decreasing the proportions of certain probes in the high-risk HPV consensus probe.

12. I have reviewed the article entitled "Human papillomavirus testing by hybrid capture appears to be useful in triaging women with a cytologic diagnosis of atypical squamous cells of undetermined significance," which was published in the American Journal of Obstetrics and Gynecology in March of 1995 (Cox *et al.*, 1995, *Am. J. Obstet. Gynecol.* 172:946-54).

13. At the time the Cox *et al.*, 1995 reference was published, a person of ordinary skill in the art would have appreciated that hybrid capture high-risk HPV probe reagents such as the one disclosed by Cox *et al.* would detectably hybridize to the genomic sequence of a low-risk HPV type, and moreover, would generate false positives with respect to low-risk HPV types.

14. At the time the above-described application was filed, a person of ordinary skill in the art would have expected a high-risk HPV consensus probe to detectably hybridize to the genomic sequence of both low-risk and high-risk HPV types under low stringency conditions, and to not detectably hybridize to the genomic sequence of either low-risk HPV types or high-risk HPV types other than those used to generate the high-risk HPV consensus probe under high stringency conditions.

15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed: _____

Gerard J. Nuovo

Dated: _____

9.18.06

To: Jack Kennealy and Ilse Light; ONCOR
 From: Gerard Nuovo, MGN Medical Consultants
 Re: HPV in situ study
 Date:

Dear Jack and Ilse:

I would like to summarize the data/findings that relate to the different issues we discussed recently:

- o HPV 42, 43, and 44 data. This is summarized in the tables included with this letter. It is clear from this data that high copy HPV 6/11, 42, 43, or 44 positive cases can cross hybridize with the "high risk" ONCOR probe cocktail (each at 500 ng/ml) at low stringency (1XSSC, 2% BSA, and 45°C for 5 min). Our options are to increase the stringency and/or decrease the concentration of the various probes. To do the latter, we must know the hybridization profiles of the different HPV types.
- o Cross hybridization profiles of the different HPV types. I performed in situ hybridization using 500 ng/ml of the ONCOR probe cocktails with tissues known to contain a variety of HPV types. The data follows:

Cross hybridization patterns*

	HPV 16	HPV 18	HPV 31	HPV 33	HPV 35	HPV 51
6/11	2+	0	1+	0	weak	0
18	0	3+	0	0	0	
45	0	2+	0	weak	0	0
52	0	0	0	0	2+	0
56	1+	0	1+	0	weak	0

* Done at low stringency.

- o With this information, we did two sets of experiments:
 - a) High stringency wash;
 - b) Relationship of signal for HPV 6/11+ case with different concentrations of HPV 16 probes. I chose HPV 16, of course, because it is the one most responsible for the signal with the HPV 6/11 tissues. The data follow:

(A)

SIGNAL INTENSITY Varying stringency

Case	HPV type	specific HPV type	Digene Omniprobe	ONCOR consensus
		Low stringency*		
5	6/11	3+ (Digene)	3+	2+
		High stringency*		
5	6/11	3+ (Digene)	3+	0
17	56	Low stringency		
		3+ (Digene)	3+	3+
17	56	High stringency		
		3+ (Digene)	3+	0

* Low stringency = 5 minutes at 45°C in 1XSSC and 2% BSA

*High stringency = 10 minutes at 62°C in 0.1XSSC and 2% BSA

Obviously, the high stringent conditions eliminate the signal with the HPV 6/11 tissue but also cause us to lose the signal with an important "novel" type - HPV 56.

The next strategy was to see if we could eliminate the signal with the HPV 6/11 tissue at low stringency using a lower concentration of the "culprit" HPV 16. The data follows:

(B)

HPV 16 concentration study

	500 ng/ml	200 ng/ml	100 ng/ml	50 ng/ml	33 ng/ml	25 ng/ml
6/11 hi*	2+	weak	0	0	0	0
16 hi*	3+	3+	2+	weak	weak	weak
16 low*	1+	1+	1+	0	0	0

* The HPV 6/11 tissue was a cervical low grade SIL with strongest signal I have ever seen. Of course, this was done because if we can eliminate the signal with it, then lower copy HPV 6/11 tissues will also be scored as negative.

In summary, it is clear that a concentration for HPV 16 in the probe cocktail of 100-200 ng/ml should greatly facilitate eliminating the HPV 6/11 cross over.

◇ True blue reagent and hybrisol. I used the hybrisol and true blue for the data just reported. Clearly, these work very well.

- ◇ Novel types (specifically HPV 39,58,59, and 68). My assistant and I are beginning the experiments using PCR to identify and type new HPVs based on the published endonuclease profiles. I've included in this report a paper which describes the identification of HPV 70. As you can see from the abstract, this type strongly cross reacts with HPV 39,59, and 68. Clearly, if HPV 70 could be included in the ONCOR cocktail, this should permit detection of these types. Hopefully, I will find HPV 70 in my collection. A quick and simple way to enhance the ONCOR system is to prepare several oligos of 40-50 bp from the HPV 70 sequence and include this in the cocktail.
- ◇ Hybrid capture system. I'll briefly review this information, as it was discussed in my recent Email. The Hybrid capture system is done at high stringency, and one must use >4,000 pg of HPV 6/11 to see a signal with the high risk cocktail. Most HPV 6/11 cervical warts would not have such a high copy number. I think the key to stress is that the ONCOR system is superior to the Hybrid capture system in several ways:
 - ⇒ It detects clinical infection whereas the Digene system also detects subclinical infection;
 - ⇒ Because it is done at low stringency, it can detect a greater range of novel high risk HPV types and still avoid detecting the low risk types by using the correct proportion of HPV types in the cocktail;
 - ⇒ The ONCOR system allows the pathologist to identify the infected cell type (ASCUS, dysplasia, eg) whereas the Digene system does not.

SUMMARY

- * The key data is the cross hybridization of HPV 6/11 with the high risk types and the realization that we can eliminate the HPV 6/11 signal by adjusting the concentration of the HPV 16 probe and still maintain low stringent conditions.
- * The ONCOR system as it stands now does an excellent job in detecting the "still novel" types (ie, not HPVs 16,18,31,33,35,45,51,52, or 56); these must include HPVs 39,58,59, and 68. It hasn't missed one yet! We should maintain low stringency to continue to make this a selling point of the ONCOR system. The high stringency Digene hybrid capture system can't detect these novel types; this is why they are adding yet more types. The inclusion of HPV 70 (all or part) should allow the ONCOR system to perform even better with most of these "still novel" HPV types.
- * If we go to high stringency, we will lose the signal of many of these novel types unless we get probes for all or most of them. Although I'll try to isolate

these novel types, I don't think the ONCOR system needs them to be successful whereas the Digene system does need them.

SIGNAL INTENSITY**High risk types****Low stringency**

Case	HPV type	specific HPV type*	Digene Omniprobe	ONCOR consensus
1	16	3+	2+	3+
2	16	weak	1+	1+
3	16	2+	2+	2+
4	16	2+	2+	2+
5	18	3+	1+	3+
6	18	3+	3+	3+
7	31	3+	1+	3+
8	33	3+	3+	3+
9	33	3+	3+	3+
10	35	3+	3+	3+
11	45	3+ (digene)	3+	3+
12	45	2+ (digene)	2+	2+
13	51	2+	2+	2+
14	51	1+	1+	1+
15	52	2+ (digene)	2+	1+
16	52	3+ (digene)	3+	2+
17	56	3+ (digene)	2+	2+
18	56	3+ (digene)	3+	3+
19	novel, 45R	45 = 3+	3+	1+
20	novel, 35R	35 = 1+	1+	1+
21	novel, many types	6,16,31/33/35+	3+	3+
22	novel, 16R	1+ (digene)	1+	1+

* The specific HPV type is from the genomic ONCOR probe except for HPV types 45, 52, novel types, and 56 where the Digene probe was used.

The signal intensity varied from 1+ (weak signal, light blue), 2+ (moderate signal, blue), and 3+ (intense signal, blue-black).

SIGNAL INTENSITY**Low risk types****Low stringency**

Case	HPV type	specific HPV type	Digene Omniprobe	ONCOR consensus
1	6/11	3+ (Digene)	3+	1+
2	6/11	2+ (Digene)	2+	0
3	6/11	2+ (Digene)	2+	0
4	6/11	1+ (Digene)	1+	0
5	6/11	3+ (Digene)	3+	2+
6	6/11	2+ (Digene)	2+	0
7	42	2+ (Digene)	2+	0
8	43	1+ (Digene)	1+	0
9	44	3+ (Digene)	3+	1+

NEW DATA
ONCOR consensus probe cocktail data
Low stringency

	Digene probe*	Cocktail 1**	Cocktail 2	Cocktail 3
2	0 (3+ HPV 2)	0	0	0
6/11	3+	2+	0	0
6/11	3+	2+	1+	weak
6/11	3+	1+	0	0
6/11	3+	3+	0	0
6/11	2+	1+	0	0
6/11	1+	0	0	0
6/11	3+	1+	0	0
6/11	1+	0	0	0
6/11	3+	1+	0	0
42	2+	ND	0	0
43	2+	ND	0	0
44	2+	0	0	0
16	1+	1+	1+	1+
16	3+	3+	3+	2+
16	3+	3+	3+	3+
16	2+	2+	2+	1+
16	1+	1+	1+	1+
18	3+	3+	3+	3+
31	2+	2+	2+	2+
31	3+	3+	3+	3+
31	3+	3+	3+	3+
33	3+	3+	3+	3+
45	3+	3+	3+	3+
56	3+	2+	2+	1+
56	3+	2+	1+	1+
still novel	3+ (45 related)	3+	3+	2+
	2+ (16 related)	2+	1+	1+

* The digene probe is their type specific probe.

** Cocktail 1 has 500 ng/ml of HPV 16, cocktail 2 has 200 ng/ml HPV 16, and cocktail 3 has 100 ng/ml. Each cocktail has 500 ng/ml of HPVs 18,33,35, and 51 plus 200 ng/ml of HPV 31.

To: Jack Kennealy, PhD and Ilse Light
From: Gerard Nuovo
Re: HPV testing
Date:

Dear Ilse and Jack:

I am sending some more information with regards to HPV's 45,52, and 56. As you can see, HPV 56 can be detected by HPV 31, HPV 52 is most related to HPV 33, and HPV 45 is most related to HPV 18. You may recall that HPV 31 did detect HPV 56 and HPV 18 did detect HPV 45 when I did these tests using the individual ONCOR genomic probes. The fact that HPV's 31,33, and 18 are in the ONCOR consensus probe cocktail at 500 ng/ml explains why we are detecting these types readily at low stringency. We are a bit lucky that HPV 16, which is causing most of the cross over with HPV's 6/11, appears to be less important in detecting the "novel" types (ie, HPV's 45,52,56), and the "still novel" types of HPV's 39,58,59, and 68.

I look forward to talking with you on Friday.
Sincerely,

Gerard Nuovo, MD

SUMMARY OF PREVIOUS DATA

HPV 16 concentration study

	500 ng/ml	200 ng/ml	100 ng/ml	50 ng/ml	33 ng/ml	25 ng/ml
6/11 hi*	2+	weak	0	0	0	0
16 hi*	3+	3+	2+	weak	weak	weak
16 low*	1+	1+	1+	0	0	0

* The HPV 6/11 tissue was a cervical low grade SIL with strongest signal I have ever seen. Of course, this was done because if we can eliminate the signal with it, then lower copy HPV 6/11 tissues will also be scored as negative.

SUMMARY OF PREVIOUS DATA

Detection frequencies of the different HPV types

	500 ng/ml	200 ng/ml	100 ng/ml	50 ng/ml	33 ng/ml	25 ng/ml
6/11 hi*	2+	weak	0	0	0	0
16 hi*	3+	3+	2+	weak	weak	weak
16 low*	1+	1+	1+	0	0	0

* The HPV 6/11 tissue was a cervical low grade SIL with strongest signal I have ever seen. Of course, this was done because if we can eliminate the signal with it, then lower copy HPV 6/11 tissues will also be scored as negative.

* The digene probe is their type specific probe.

** Cocktail 1 has 500 ng/ml of HPV 16, cocktail 2 has 200 ng/ml HPV 16, and cocktail 3 has 100 ng/ml. Each cocktail has 200 ng/ml of HPV's 18, 33, 39, and 31 plus 200 ng/ml of HPV 31.

To: Jack Kennealy, PhD and Ilse Light
FAX: 301-963-1436
From: Gerard Nuovo
Re: HPV testing
Date:

Dear Ilse and Jack:

I am re-sending the FAX of . Also included with this FAX is an update on the ONCOR probe study; note that I have included HPV 52 and another still novel type.

I look forward to talking with you at 300.
Sincerely,

Gerard Nuovo, MD

NEW DATA (n = 57)
ONCOR consensus probe cocktail data

Low stringency

	Digene probe*	Cocktail 1**	Cocktail 2	Cocktail 3
2	0 (3+ HPV 2)	0	0	0
6/11	1+	0	0	0
6/11	1+	0	0	0
6/11	2+	1+	0	0
6/11	3+	2+	0	0
6/11	3+	2+	1+	weak
6/11	3+	1+	0	0
6/11	3+	3+	0	0
6/11	3+	1+	0	0
6/11	3+	1+	0	0
6/11	1+	0	0	0
6/11	1+	0	0	0
42	2+	-	0	0
43	2+	-	0	0
44	2+	0	0	0
16	1+	1+	1+	1+
16	1+	1+	1+	1+
16	2+	2+	2+	1+
16	weak	1+	1+	1+
16	3+	3+	3+	2+
16	3+	3+	3+	3+
18	3+	3+	3+	3+
31	2+	2+	2+	2+
31	3+	3+	3+	3+
31	3+	3+	3+	3+
33	3+	3+	3+	3+
33	2+	2+	2+	2+
35	3+	3+	3+	3+
35	1+	-	-	1+
31	3+	3+	3+	3+
30	3+	3+	3+	3+
30	3+	3+	3+	3+
30	3+	3+	3+	3+
39	2+	1+	1+	1+
39	2+	2+	2+	2+
39	1+	weak	weak	weak
39	3+	3+	3+	3+
39	3+	-	3+	3+
39	1+	1+	1+	1+
45	3+	3+	3+	3+
45	3+	-	3+	3+
52	3+	3+	3+	3+
52	3+	3+	3+	3+
52	2+	2+	2+	2+
56	3+	3+	3+	3+
56	1+	1+	1+	1+
56	3+	2+	2+	1+
56	3+	2+	1+	1+
58	2+	2+	1+	1+
39	2+	2+	2+	-
68	1+	-	1+	1+
70	3+	3+	3+	2+
70	2+	ND	2+	-
70	1+	1+	1+	1+
still novel	2+ (31 related)	2+	2+	2+
	1+ (18 related)	1+	1+	1+
	1+ (18 related)	1+	1+	1+

Cross homology patterns*
Cerard Nuova, MD
MCN Medical Research Laboratories

TABLE 2.

	HPV 16	HPV 18	HPV 31	HPV 33	HPV 35	HPV 51	HPV 70	HPV 6/11
6/11	0	0	0	0	0	0	0	3+
16	3+	0	weak	0	0	0	0	0
18	0	3+	0	0	0	0	1+	0
30	0	0	0	0	weak	0	0	0
31	weak	0	3+	0	0	0	0	0
33	0	0	0	3+	0	0	0	0
35	0	0	0	0	3+	0	0	0
39	0	1+	0	0	0	0	1+	0
41	0	0	0	0	0	0	0	0
45	0	1+	0	0	0	0	1+	0
51	0	0	0	0	0	3+	0	0
52	0	0	0	0	0	0	0	0
56	1+	0	weak	0	0	0	weak	0
58	0	0	1+	1+	0	0	0	0
59	0	1+	0	0	0	0	1+	0
68	0	1+	0	0	0	0	1+	0
70	0	1+	0	0	0	0	3+	0

* Done at high stringency (60°C in 0.2XSSC and 2% bovine serum albumin for 10 min) using tissues/Pap smears known to contain the different HPV types listed in the Table. Concentration of each probe at 500 ng/ml.

CELESTIAL ID

Non Medical Research Laboratories

TABLE 3

[illegible]

39	2+	1+	1+	1+
39	2+	2+	2+	2+
39	1+	weak	weak	weak
39	3+	3+	3+	3+
39	3+	-	3+	3+
39	1+	1+	1+	1+
45	3+	3+	3+	3+
45	3+	-	3+	3+
52	3+	3+	3+	3+
52	3+	3+	3+	3+
52	2+	2+	2+	2+
56	3+	3+	3+	3+
56	1+	1+	1+	1+
56	3+	2+	2+	1+
56	3+	2+	1+	1+
58	2+	2+	1+	1+
59	2+	2+	2+	-
68	1+	-	1+	1+
70	3+	3+	2+	2+
70	2+	ND	2+	-
70	1+	1+	1+	1+
70	2+	2+	2+	2+
still novel	2+ (31 related) 1+ (18 related) 1+ (18 related)	1+	1+	1+

* The digene probe is their type specific probe.

** Cocktail 1 has 500 ng/ml of HPV 16, cocktail 2 has 200 ng/ml HPV 16, and cocktail 3 has 100 ng/ml. Each cocktail has 500 ng/ml of HPVs 18,33,35, and 51 plus 200 ng/ml of HPV 31.

Curriculum Vitae

Gerard J. Nuovo, MD

Title and current address

Professor

Dept Pathology
Ohio State University Medical Center

Education

University of Vermont (UVM)
UVM College of Medicine

Burlington, Vermont, **BA**, *summa cum laude*
Burlington, Vermont, **MD** (1983)

Postgraduate Positions

Columbia University College of P&S

Columbia University
Columbia University
SUNY, Stony Brook

Resident in Pathology, 1983-7; Chief Resident, 1987
Fellow, Gyn Pathology and Molecular Virology, 1987-9
Assistant Professor of Pathology, 1989-90
Assistant Professor of Pathology and OB/GYN
Director-Cytology, 1990-1996
Medical Director, 1996-1999;
1999-current: Professor – Anatomic Pathology

Enzo Clinical Labs
OSU Department of Pathology

Licensure

New York medical license
Ohio medical license/UPIN
DEA license
Board Certified

Number 161708-1
76400/A61837
Number AN 3092070
Anatomic Pathology; June 1987

Editorial review boards (former and present)

Journal Histochemistry and Cytochemistry; Diagnostic Molecular Pathology
Journal of Histotechnology; Frontiers in Biotechnology; Annals Diag Pathology

Inventions/patents

PCR in situ hybridization with Roche Molecular Systems (patent #5,538,871)

Awards

1. LR Jones Award for Basic Research
2. ASCAP award for resident research; 1993
3. ASCAP award for resident research; 1994
4. Third Annual Howard M. Temin Award in Clinical Science for HIV/AIDS.

Section 1: List of publications

1. Wilson DM, Nuovo GJ. Patulin production in apples decayed by *Penicillium expansum*. *Applied Microbiology* **1973**,26:124-125.
2. Wilson DM, Nuovo GJ, Darby WB. Activity of o-diphenol oxidase in post-harvest apple decay by *Penicillium expansum* and *Physalospora obtusa*. *Phytopathol* **1973**,63:1115-1118.
3. Nuovo GJ, Nagler HM, Fenoglio JJ. Arteriovenous malformation of the bladder presenting as gross hematuria. *Hum Pathol* **1986**,17:94-97.
4. Nuovo GJ, Friedman D, Silverstein SJ, Crum CP. Transcription of human papillomavirus type 16 in genital precancers. *Cancer Cells (5):Papillomaviruses*, Cold Spring Harbor Laboratory **1987**,337-342.
5. Nagai N, Nuovo GJ, Friedman D, Crum CP. Detection of papillomavirus nucleic acids in genital precancers with the *in situ* hybridization technique: a review. *Int J Gynecol Pathol* **1987**,6: 366-379.
6. Follen MM, Levine RU, Carillo E, Richart RM, Nuovo GJ, Crum CP. Colposcopic correlates of cervical papillomavirus infection. *Am J Obstet Gynecol* **1987**,157:809-814.
7. Nuovo GJ, Crum CP, Silverstein SJ. Papillomavirus infection of the uterine cervix. *Microbiol Pathogen* **1987**,3:71-78.
8. Nuovo GJ, Crum CP, DeVilliers EM, Levine RU, Silverstein SJ. The isolation of a novel human papillomavirus (HPV 51) from a cervical condyloma. *J Virol* **1988**,62:1452-1455.
9. Crum CP, Nuovo GJ, Friedman D, Silverstein SJ. Accumulation of RNA homologous to human papillomavirus type 16 open reading frames in genital precancers. *J Virol* **1988**,62:84-90.
10. Nuovo GJ, Nuovo MA, Cottrill S, Gordon S, Silverstein SJ, Crum CP. Histological correlates of clinically occult human papillomavirus infection of the uterine cervix. *Am J Surg Pathol* **1988**,12:198-204.
11. Crum CP, Nuovo GJ, Friedman D, Silverstein SJ. A comparison of biotin and isotype labelled RNA probes for *in situ* detection of papillomavirus RNA in genital neoplasms. *Lab Invest* **1988**,58:354-359.
12. Nuovo GJ, Blanco JB, Silverstein SJ, Crum CP. Histologic correlates of papillomavirus infection of the vagina. *Obstet Gynecol* **1988**,72:770-774.
13. Nuovo GJ, Silverstein SJ. Comparison of formalin, buffered formalin, and Bouin's fixation on the detection of human papillomavirus DNA extracted from genital lesions. *Lab Invest* **1988**,59:720-724.
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Section 2: List of invited chapters

1. Crum CP, Friedman D, Nuovo GJ, Silverstein SJ. Morphological correlates of genital human papillomavirus infection: Viral replication, transcription and gene expression. In: Gallo R, Hazeltine W, Klein G, ZurHausen H, eds. *Viruses and Human cancer*. **1986**, New York, Alan R. Liss:355-369.
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Section 3: List of textbooks

1. Crum CP, Nuovo GJ. Human papillomavirus and their relationship to genital tract neoplasms. New York, Raven Press **1991**.
2. Nuovo GJ. PCR *in situ* hybridization: Protocols and applications, 1st Edition. New York, Raven Press **1992**; 2nd Edition – **1994**, 3rd Edition – **1996**..
3. Nuovo GJ. Cytopathology of the female genital tract: An integrated approach. Baltimore, Williams and Wilkins **1993**.

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Section 4: List of funding

#	Source	Time period	Amount
1.	NIH Training Fellowship-(5T32-CA09503)	1987-88	\$25,000
2.	Lewis Foundation	1989-92	\$200,000
3.	Life Technologies, Inc	1990-91	\$25,000
4.	ONCOR, Corporation	1990-93	\$30,000
5.	Roche Molecular Systems	1993-94	\$20,000
6.	College of American Pathologists	1993-94	\$25,000
7.	Procter and Gamble Company	1993-94	\$25,000
8.	Perkin-Elmer Corporation	1993-96	\$75,000
9.	Center for Biotechnology, SUNY	1993-96	\$100,000
10.	NIH Arthritis and Musculoskeletal disease, (R01AR3327810) collaborator	1993-98	\$656,971
11.	ONCOR Corporation	1996-98	\$60,000
12.	Schering Plough Corporation	1996-99	\$80,000
13.	Becton Dickinson, Inc	1996-99	\$110,000
14.	Johnson and Johnson, Inc	1996-99	\$60,000
15.	Genetics Institute	1996-98	\$55,000
16.	NCI; RF project # 739453; collaborator Devising therapies for AIDS CNS lymphomas	1999-04	\$434,200
17.	NCI; RO1 HL-00-012 T-lymphocytes, latent virus, and emphysema pathogenesis - co-Principal investigator	2001-03	\$663,188
18.	Zymogenetics; co-PI; IL21 expression in NHLs	2001-02	\$32,800
19.	The Lewis Foundation In utero infections	2003-6	\$10,000

20. NCI, R21 CA108157-01; Biomodulation of capecitabine by docetaxel in non-small cell lung cancer; collaborator 2004-07 \$201,255
The only grant of Dr. Villalona's that you are appointed to is his R21 titled "Biomodulation of capecitabine by docetaxel in non-small cell lung cancer" (Project 746715). The dates of this grant are 4/22/04 - 3/31/07, the amount of annual direct costs is \$205,000, and you are appointed at 10% effort which equates to 1.2 calendar months.
21. **R01: IL-15 and Innate Immunity in Acute Graft Versus Host Disease (pending); collaborator**
22. **MyGene Corporation; Detection of HPV DNA by a microchip array assay;** 2005-2006 \$40
23. **RO1: Conduct disorder and pregnancy: HPA axis activity, fetal programming, and mothering; Co-Pi** pending \$2,985,223